K082588

510(k) Summary

DEC 11 2009

Submitted by:
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Device name: GammaLōc® System, Accessory to Dilon 6800 Gamma Camera
Common name: Gamma Camera System
Classification name: Scintillation (Gamma) Camera
Classification, Regulation, Panel and Procode:
Class 1, CFR 892.1100, Radiology Panel, IYX

Device Description:
The GammaLōc® System is a lesion localization accessory to the Dilon 6800 Gamma Camera, previously cleared under K984466 (originally named Dilon 2000 Digital Gamma Camera). The Dilon Gamma Camera is a high resolution, small field of view, portable gamma camera for use in imaging radiopharmaceuticals consisting of three primary components: the detector head, the gantry arm and the mobile cabinet. There are no changes to the gamma camera in this submission.

Substantially equivalent to:
The GammaLōc® System integrates the same procedure steps and consumables from legally marketed predicates with functional guided biopsy to provide a gamma-guided stereotactic lesion localization accessory to the Dilon 6800 Gamma Camera. The Dilon GammaLōc® System integrates the gamma camera image with the three steps of a localization procedure that has evolved from the experiences with stereotactic x-ray or MRI guided systems: localization, immobilization/correlation, and verification. The GammaLōc® System use for functional gamma guidance is equivalent to using a gamma probe, currently used to guide biopsy and surgery in clinics today, although gamma probes are not imaging systems. The consumable components have predicates to which the GammaLōc® System components are equivalent and the sterile disposables are considered a Convenience Kit.

Indications for use:
The GammaLōc® System is a lesion localization accessory for the Dilon 6800 Gmma Camera. This stereotactic localization system gives the physician the capability to perform needle biopsy of lesions determined to be suspicious through gamma imaging.

Summary of Testing:
The performance of the GammaLōc® System has been tested to establish that it can be used for localization of suspected tumor sites in the breast. Verification tests were performed on various components of the system to determine their individual performance. Validation tests were also performed on the integrated unit to determine the system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Dilon Technologies, Inc.
% Ms. Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
STILLWATER MN 55082

JAN 2 1 2010

Re: K082588
Trade/Device Name: GammaLöc® System
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) Camera
Regulatory Class: I
Product Code: IYX
Dated: October 7, 2009
Received: October 9, 2009

Dear Ms. Duncan:

This letter corrects our substantially equivalent letter of December 11, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health